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510(k) Summary
510(k) Number K082627

MinXray, Inc.
3611 Commercial Avenue –
Northbrook, Illinois 60062, USA
Toll Free 1-800-221-2245 (USA & Canada)
Tel. 1-847-564-0323
Fax 1-847-564-9040
Date Prepared: September 4, 2008
Contact: Keith Kretchmer, President

1. **Identification of the Device:**
   Proprietary-Trade Name: CMDR-1S Digital Diagnostic X-Ray System (Mobile)
2. **Classification Name:** Mobile x-ray system, Product Code 90 IZL and Solid State X-Ray Imager (Flat Panel/Digital Imager) 90 MQB,
   Common/Usual Name: Digital Mobile Diagnostic X-Ray System

3. **Equivalent legally marketed device**: 510(k) Number K042361 DIGITAL PORTABLE X-RAY UNITS, MODEL SP-HF-4.0 D, SEDECAL USA, INC

4. **Indications for Use (intended use)** This digital radiographic system is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.

5. **Description of the Device**: This represents the straightforward interconnection of two FDA cleared devices: The MinXray HF120/60H PowerPlus™ (K040046) and the Canon CXDI-50G Solid State Imager (K031447). MinXray HF120/60H PowerPlus™ is a portable unit which operates from 120 V 50-60~ AC. The generator unit utilizes a high frequency inverter and can be mounted to a tripod or support arm. The usual safety precautions regarding the use of x-rays must be observed by the operator. The digital panel features Canon's large-area flat panel technology in a sleek and compact unit. The portable CXDI-50G provides digital X-ray image capture for a wide range of applications. The lightweight design, generous imaging area, and fast processing times of the detector make it easy to capture high quality diagnostic images for routine diagnosis, as well as challenging trauma and bedside exams. It's a portable solution for a faster, more streamlined approach to digital radiography.

6. **Safety and Effectiveness, comparison to predicate device**. The results of bench testing indicates that the new device is as safe and effective as the predicate devices. Proper system operation is fully verified upon installation.

7. Substantial Equivalence Chart

Characteristic	510(k) Number K042361 DIGITAL PORTABLE X-RAY UNITS, MODEL SP-HF-4.0 D, Applicant SEDECAL USA, INC	CMDR-1S Digital Diagnostic X-Ray System (Mobile)
Intended Use:	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.	SAME
Configuration	Mobile System	SAME
Generator	High Frequency	SAME
Performance Standard	21 CFR 1020.30	SAME
Generator	High frequency made by Sedecal in Spain, 300 khz.	Uses high frequency generator made by Mikasa X-Ray in Japan. 80 khz.
Power Source	120 V 50/60 Hz AC 20 amp	SAME
Digital Panel	CANON CXDI 50G	SAME

7. Conclusion

After analyzing bench tests, it is the conclusion of MinXray Inc that the MinXray CMDR-1S Digital Diagnostic X-Ray System is as safe and effective as the predicate device, have few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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MinXray, Inc.
% Mr. Daniel Kamm, P.E.
Principal Consultant
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K082627
Trade/Device Name: CMDR-1S Digital Diagnostic X-Ray System (Mobile)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: September 5, 2008
Received: September 13, 2008

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082627

Device Name: CMDR-1S Digital Diagnostic X-Ray System (Mobile)

Indications For Use:
This digital radiographic system is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays..

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082627